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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

JENNIFER CAMPBELL TATE,

Plaintiff,

Case No. CV-15-2139-PHX-DGC

v.

C. R. BARD, INC., a foreign corporation;
and BARD PERIPHERAL VASCULAR,
INC., an Arizona Corporation,

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND DEFENSES TO
PLAINTIFF'S COMPLAINT**

Defendants.

Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”) (Bard and BPV are collectively “Defendants”) answer Plaintiff’s Complaint (“Plaintiff’s Complaint”) of Plaintiff Jennifer Campbell Tate (“Plaintiff”) as follows:

PARTIES

1. To the extent the allegations in Paragraph 1 of the Plaintiff’s Complaint purport to cast liability upon Defendants, either directly or indirectly, those allegations are denied. Defendants are without information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 1 of the Plaintiff’s Complaint and, on that basis, deny them.

2. Defendants deny that Bard is a Delaware corporation. Defendants admit that Bard is a New Jersey corporation and that Bard is authorized to do business, and does business, in the State of Pennsylvania, including Allegheny County, Pennsylvania. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including filters under the trademark G2® Filter System. Bard denies any remaining allegations contained in Paragraph 2 of Plaintiff’s Complaint.

3. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in the State of Pennsylvania, including Allegheny County, Pennsylvania. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants deny any remaining allegations contained in Paragraph 3 of Plaintiff’s Complaint.

4. The allegations contained in Paragraph 4 of Plaintiff’s Complaint are not directed at Bard or BPV, and, as a result, no response is required of these Defendants. To the extent Paragraph 4 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

JURISDICTION AND VENUE

5. Defendants do not contest that the injuries and damages alleged within Plaintiff's Complaint exceed the jurisdictional limit of this Court. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Western District of Pennsylvania.

6. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, venue appears to be proper in the United States District Court for the Western District of Pennsylvania.

FACTUAL ALLEGATIONS

7. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny the remaining allegations contained in Paragraph 7 of Plaintiff's Complaint.

8. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants further admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants deny any remaining allegations contained in Paragraph 8 of Plaintiff's Complaint.

9. Defendants deny the allegations contained in Paragraph 9 of Plaintiff's Complaint, including all sub-parts thereof.

1 10. Defendants lack knowledge or information sufficient to form a belief as to the
2 truth of the allegation regarding the time frame when inferior vena cava filters were first
3 introduced on the market or the identity of manufacturers of inferior vena cava filters.
4 Defendants deny any remaining allegations of Paragraph 10 of Plaintiff's Complaint.

5 11. Defendants admit that inferior vena cava filters are intended to prevent injury or
6 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
7 that inferior vena cava filters may be designed for permanent placement, temporary
8 placement, or both. Defendants deny any remaining allegations of Paragraph 11 of Plaintiff's
9 Complaint.

10 12. Defendants admit that the inferior vena cava is a large vein that receives blood
11 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
12 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
13 human health, including sometimes death. Defendants deny any remaining allegations of
14 Paragraph 12 of Plaintiff's Complaint.

15 13. Defendants admit that certain people are at an increased risk for the
16 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information
17 to form a belief as to the truth of the allegations as stated regarding the various risk factors
18 which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus
19 deny them. Defendants deny any remaining allegations of Paragraph 13 of Plaintiff's
20 Complaint.

21 14. Defendants admit that patients at a high risk for developing deep vein
22 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
23 including but not limited to the medications listed in Paragraph 14 of Plaintiff's Complaint.
24 Defendants further admit that inferior vena cava filters may also be used to treat patients who
25 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
26 lack knowledge or information sufficient to form a belief as to the truth of any remaining
27 allegations contained in Paragraph 14 of Plaintiff's Complaint and, on that basis, deny them.
28

1 15. Defendants lack knowledge or information or information sufficient to form a
2 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters
3 were first introduced on the market. Defendants also lack knowledge or information
4 sufficient to form a belief as to the truth of the allegation regarding the time frame when
5 optional or retrievable filters came to be marketed or the other allegations regarding optional
6 or retrievable filters marketed by other manufacturers. Defendants admit that the Recovery®
7 and G2® Filters were cleared by the FDA for optional use as retrievable inferior vena cava
8 filters. Defendants deny any remaining allegations contained in Paragraph 15 of Plaintiff's
9 Complaint.

10 16. Defendants admit that the Recovery® Filter was cleared by the FDA for
11 permanent placement on November 27, 2002, pursuant to an application submitted under
12 Section 510(k) of the Food, Drug and Cosmetic Act of 2005. The allegations pertaining to
13 the requirements of Section 510(k) are legal conclusions of law to which no answer is
14 required. Defendants deny any remaining allegations contained in Paragraph 16 of Plaintiff's
15 Complaint, including any allegations contained in Footnote 1.

16 17. Defendants admit that the Recovery® Filter was cleared by the FDA for
17 retrievable placement on July 25, 2003, pursuant to an application submitted under
18 Section 510(k) of the Food, Drug and Cosmetic Act of 2005. Defendants deny any remaining
19 allegations contained in Paragraph 17 of Plaintiff's Complaint.

20 18. Defendants deny the allegations contained in Paragraph 18 of Plaintiff's
21 Complaint as stated.

22 19. Defendants deny the allegations contained in Paragraph 19 of Plaintiff's
23 Complaint.

24 20. Defendants admit that the Recovery® Filter consists of twelve, shape-memory
25 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the
26 twelve wires form two levels of filtration for emboli: the legs provide the lower level of
27
28

1 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining
2 allegations contained in Paragraph 20 of Plaintiff's Complaint.

3 21. Defendants admit that a nickel-titanium alloy named Nitinol is used in the
4 manufacture of the Recovery Filter and further admit that Nitinol contains shape memory.
5 However, to the extent Paragraph 21 purports to cast liability either directly or indirectly
6 upon Defendants, said Paragraph is expressly denied.

7 22. Defendants admit that the Recovery® Filter was designed to be inserted
8 endovascularly. Defendants further admit that the Recovery® Filter is designed to be
9 delivered via an introducer sheath, which is included in the delivery system for the device.
10 Defendants deny any remaining allegations of Paragraph 22 of Plaintiff's Complaint.

11 23. Defendants deny the allegations contained in Paragraph 23 of Plaintiff's
12 Complaint.

13 24. Defendants deny the allegations contained in Paragraph 24 of Plaintiff's
14 Complaint.

15 25. Defendants deny the allegations contained in Paragraph 25 of Plaintiff's
16 Complaint.

17 26. Defendants deny the allegations contained in Paragraph 26 of Plaintiff's
18 Complaint.

19 27. Defendants deny the allegations contained in Paragraph 27 of Plaintiff's
20 Complaint.

21 28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's
22 Complaint.

23 29. Defendants deny the allegations contained in Paragraph 29 of Plaintiff's
24 Complaint.

25 30. Defendants admit that there are various well-documented complications that
26 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
27 Defendants further admit that it is well documented that many instances of filter fracture
28

1 and/or migration result in no complications whatsoever but, rather, are completely
2 asymptomatic. By way of further response, Defendants state that there are incidents related
3 to the occurrence of known complications associated with every manufacturer of inferior
4 vena cava filters. Defendants deny the remaining allegations of Paragraph 30 of Plaintiff's
5 Complaint, including all sub-parts thereof.

6 31. Defendants deny the allegations contained in Paragraph 31 of Plaintiff's
7 Complaint as stated.

8 32. Defendants deny the allegations contained in Paragraph 32 of Plaintiff's
9 Complaint.

10 33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's
11 Complaint as stated.

12 34. Defendants deny the allegations contained in Paragraph 34 of Plaintiff's
13 Complaint as stated.

14 35. Defendants admit that, as part of their continuing efforts to constantly evaluate
15 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
16 continually striving to improve the life-saving performance of those devices. The G2® Filter
17 was developed in furtherance of those efforts. Defendants admit the G2® Filter System was
18 cleared by the United States Food and Drug Administration for permanent placement
19 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic
20 Act in 2005. Defendants further admit that the G2® Filter System was subsequently cleared
21 by the United States Food and Drug Administration for retrievable placement pursuant to an
22 application submitted under Section 510(k) of the Food, Drug and Cosmetic Act in 2008.
23 Defendants deny the remaining allegations contained in Paragraph 35 of Plaintiff's
24 Complaint.

25 36. Defendants deny the allegations contained in Paragraph 36 of Plaintiff's
26 Complaint as stated.

1 37. Defendants admit that certain marketing materials for the G2® Filter contained
2 the words “enhanced fracture resistance,” “improved centering,” and “increased migration
3 resistance.” Defendants deny the remaining allegations contained in Paragraph 37 of
4 Plaintiff’s Complaint.

5 38. Defendants deny the allegations contained in Paragraph 38 of Plaintiff’s
6 Complaint

7 39. Defendants deny the allegations contained in Paragraph 39 of Plaintiff’s
8 Complaint.

9 40. Defendants admit that there are various well-documented complications that
10 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
11 Defendants further admit that it is well documented that many instances of filter fracture
12 and/or migration result in no complications whatsoever but, rather, are completely
13 asymptomatic. By way of further response, Defendants state that there are incidents related
14 to the occurrence of known complications associated with every manufacturer of inferior
15 vena cava filters. Defendants deny the remaining allegations of Paragraph 40 of Plaintiff’s
16 Complaint, including all sub-parts thereof.

17 41. Defendants admit that there are various well-documented complications that
18 may occur as the result of the fracture and/or migration of any inferior vena cava filter.
19 Defendants state that there are incidents related to the occurrence of known complications
20 associated with every manufacturer of inferior vena cava filters. By way of further response,
21 Defendants state that information available in the public domain, including the FDA MAUDE
22 database, is not a comprehensive analysis of all instances of such complications. Defendants
23 deny the remaining allegations of Paragraph 41 of Plaintiff’s Complaint.

24 42. Defendants admit that there are various well-documented complications that
25 may occur as the result of the fracture and/or migration of any inferior vena cava filter.
26 Defendants state that there are incidents related to the occurrence of known complications
27 associated with every manufacturer of inferior vena cava filters. By way of further response,
28

1 Defendants state that information available in the public domain, including the FDA MAUDE
2 database, is not a comprehensive analysis of all instances of such complications. Defendants
3 deny the remaining allegations of Paragraph 42 of Plaintiff's Complaint.

4 43. Defendants deny the allegations contained in Paragraph 43 of Plaintiff's
5 Complaint.

6 44. Defendants deny the allegations contained in Paragraph 44 of Plaintiff's
7 Complaint.

8 45. Defendants deny the allegations contained in Paragraph 45 of Plaintiff's
9 Complaint as stated.

10 46. Defendants deny the allegations contained in Paragraph 46 of Plaintiff's
11 Complaint.

12 47. Defendants deny the allegations contained in Paragraph 47 of Plaintiff's
13 Complaint, including all sub-parts thereof.

14 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's
15 Complaint.

16 49. Defendants deny the allegations contained in Paragraph 49 of Plaintiff's
17 Complaint.

18 50. Defendants deny the allegations contained in Paragraph 50 of Plaintiff's
19 Complaint as stated.

20 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's
21 Complaint as stated.

22 52. Defendants deny the allegations contained in Paragraph 52 of Plaintiff's
23 Complaint.

24 53. Defendants deny the allegations contained in Paragraph 53 of Plaintiff's
25 Complaint.

1 54. Defendants admit that Bard received a warning letter from the FDA's Los
2 Angeles District Office dated July 13, 2015. Defendants deny the remaining allegations of
3 Paragraph 54 of Plaintiff's Complaint.

4 55. Defendants deny the allegations contained in Paragraph 55 of Plaintiff's
5 Complaint as stated.

6 56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's
7 Complaint as stated.

8 57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's
9 Complaint as stated.

10 58. Defendants deny the allegations contained in Paragraph 58 of Plaintiff's
11 Complaint as stated.

12 59. Defendants are without knowledge or information sufficient to form a belief as
13 to the truth of the allegations contained in Paragraph 59 of Plaintiff's Complaint and, on that
14 basis, deny them.

15 60. Defendants admit that Bard owns a facility where vena cava filters are
16 manufactured and that filters under the trademark G2® Filter System were manufactured at
17 that facility. Defendants further admit that BPV designs, sells, markets, and distributes
18 inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under
19 the trademark G2®Filter System. Defendants deny any remaining allegations contained in
20 Paragraph 60 of Plaintiff's Complaint.

21 61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's
22 Complaint.

23 62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's
24 Complaint.

25 63. Defendants deny the allegations contained in Paragraph 63 of Plaintiff's
26 Complaint.

64. Defendants deny the allegations contained in Paragraph 64 of Plaintiff's Complaint.

65. Defendants deny the allegations contained in Paragraph 65 of Plaintiff's Complaint.

66. Defendants deny the allegations contained in Paragraph 66 of Plaintiff's Complaint.

67. Defendants deny the allegations contained in Paragraph 67 of Plaintiff's Complaint.

68. Defendants deny the allegations contained in Paragraph 68 of Plaintiff's Complaint.

69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's Complaint.

70. Defendants deny the allegations contained in Paragraph 70 of Plaintiff's Complaint.

71. Defendants deny the allegations contained in Paragraph 71 of Plaintiff's Complaint.

72. Defendants deny the allegations contained in Paragraph 72 of Plaintiff's Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's Complaint.

COUNT I – NEGLIGENCE

74. Defendants incorporate by reference their responses to Paragraphs 1-73 of Plaintiff's Complaint as if fully set forth herein.

75. Defendants deny the allegations of Paragraph 75 of Plaintiff's Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and

1 distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed
2 filters under the trademark G2® Filter Systems. Defendants deny any remaining allegations
3 contained in Paragraph 75 of Plaintiff's Complaint.

4 76. Defendants are without knowledge or information sufficient to form a belief as
5 to the truth of the allegations regarding the trade name of any inferior vena cava filter
6 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining
7 allegations of Paragraph 76 of Plaintiff's Complaint.

8 77. The allegations contained in Paragraph 77 regarding Defendants' duty are legal
9 conclusions of law, and no answer is required. To the extent a response is required,
10 Defendants deny the allegations. Defendants deny the remaining allegations contained in
11 Paragraph 77 of Plaintiff's Complaint.

12 78. Defendants deny the allegations contained in Paragraph 78 of Plaintiff's
13 Complaint.

14 79. Defendants deny the allegations contained in Paragraph 79 of Plaintiff's
15 Complaint, including all sub-parts thereof.

16 80. Defendants deny the allegations contained in Paragraph 80 of Plaintiff's
17 Complaint.

18 81. Defendants deny the allegations contained in Paragraph 81 of Plaintiff's
19 Complaint.

20 82. Defendants deny the allegations contained in Paragraph 82 of Plaintiff's
21 Complaint, including all sub-parts thereof.

22 83. Defendants deny the allegations contained in Paragraph 83 of Plaintiff's
23 Complaint.

24 **COUNT II – NEGLIGENT FAILURE TO WARN**

25 84. Defendants incorporate by reference their responses to Paragraphs 1-83 of
26 Plaintiff's Complaint as if fully set forth herein.

1 85. Defendants deny the allegations of Paragraph 85 of Plaintiff's Complaint as
2 stated. By way of further response, Defendants admit that Bard owns a facility where vena
3 cava filters are manufactured and that filters under the trademark G2® Filter Systems were
4 manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and
5 distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed
6 filters under the trademark G2® Filter Systems. Defendants deny any remaining allegations
7 contained in Paragraph 85 of Plaintiff's Complaint.

8 86. Defendants deny the allegations contained in Paragraph 86 of Plaintiff's
9 Complaint.

10 87. Defendants deny the allegations contained in Paragraph 87 of Plaintiff's
11 Complaint.

12 88. The allegations contained in Paragraph 88 regarding Defendants' duty are legal
13 conclusions of law, and no answer is required. To the extent a response is required,
14 Defendants deny the allegations. Defendants deny the remaining allegations contained in
15 Paragraph 88 of Plaintiff's Complaint.

16 89. The allegations contained in Paragraph 89 regarding Defendants' duty are legal
17 conclusions of law, and no answer is required. To the extent a response is required,
18 Defendants deny the allegations. Defendants deny the remaining allegations contained in
19 Paragraph 89 of Plaintiff's Complaint.

20 90. Defendants deny the allegations contained in Paragraph 90 of Plaintiff's
21 Complaint.

22 91. Defendants deny the allegations contained in Paragraph 91 of Plaintiff's
23 Complaint.

24 92. Defendants deny the allegations contained in Paragraph 92 of Plaintiff's
25 Complaint.

26 93. Defendants deny the allegations contained in Paragraph 93 of Plaintiff's
27 Complaint.

94. Defendants deny the allegations contained in Paragraph 94 of Plaintiff's Complaint.

95. Defendants deny the allegations contained in Paragraph 95 of Plaintiff's Complaint.

96. Defendants deny the allegations contained in Paragraph 96 of Plaintiff's Complaint.

COUNT III – STRICT LIABILITY FAILURE TO WARN

97. Defendants incorporate by reference their responses to Paragraphs 1-96 of Plaintiff's Complaint as if fully set forth herein.

98. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 98 of Plaintiff's Complaint.

99. Defendants deny the allegations contained in Paragraph 99 of Plaintiff's Complaint.

100. The allegations contained in Paragraph 100 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 100 of Plaintiff's Complaint.

101. Defendants deny the allegations contained in Paragraph 101 of Plaintiff's Complaint.

1 102. Defendants deny the allegations contained in Paragraph 102 of Plaintiff's
2 Complaint.

3 103. Defendants deny the allegations contained in Paragraph 103 of Plaintiff's
4 Complaint.

5 104. Defendants deny the allegations contained in Paragraph 104 of Plaintiff's
6 Complaint.

7 105. Defendants deny the allegations contained in Paragraph 105 of Plaintiff's
8 Complaint.

9 106. Defendants deny the allegations contained in Paragraph 106 of Plaintiff's
10 Complaint.

11 107. Defendants deny the allegations contained in Paragraph 107 of Plaintiff's
12 Complaint.

13 108. Defendants deny the allegations contained in Paragraph 108 of Plaintiff's
14 Complaint.

15 **COUNT IV – STRICT PRODUCTS LIABILITY DESIGN DEFECTS**

16 109. Defendants incorporate by reference their responses to Paragraphs 1-108 of
17 Plaintiff's Complaint as if fully set forth herein.

18 110. Defendants are without knowledge or information sufficient to form a belief as
19 to the truth of the allegations regarding the trade name of any inferior vena cava filter
20 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
21 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
22 the trademark G2® Filter System were manufactured at that facility. Defendants further
23 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
24 designed, sold, marketed, and distributed filters under the trademarks G2® Filter System.
25 Defendants deny any remaining allegations contained in Paragraph 110 of Plaintiff's
26 Complaint.

111. Defendants deny the allegations contained in Paragraph 111 of Plaintiff's Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of Plaintiff's Complaint.

113. Defendants deny the allegations contained in Paragraph 113 of Plaintiff's Complaint.

114. Defendants deny the allegations contained in Paragraph 114 of Plaintiff's Complaint.

115. Defendants deny the allegations contained in Paragraph 115 of Plaintiff's Complaint.

116. Defendants deny the allegations contained in Paragraph 116 of Plaintiff's Complaint.

117. Defendants deny the allegations contained in Paragraph 117 of Plaintiff's Complaint.

COUNT V – STRICT LIABILITY MANUFACTURING DEFECT

118. Defendants incorporate by reference their responses to Paragraphs 1-117 of Plaintiff's Complaint as if fully set forth herein.

119. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 119 of Plaintiff's Complaint.

1 120. Defendants deny the allegations contained in Paragraph 120 of Plaintiff's
2 Complaint.

3 121. Defendants deny the allegations contained in Paragraph 121 of Plaintiff's
4 Complaint.

5 122. Defendants deny the allegations contained in Paragraph 122 of Plaintiff's
6 Complaint.

7 123. Defendants deny the allegations contained in Paragraph 123 of Plaintiff's
8 Complaint.

9 **COUNT VI – BREACH OF EXPRESS WARRANTY**

10 124. Defendants incorporate by reference their responses to Paragraphs 1-123 of
11 Plaintiff's Complaint as if fully set forth herein.

12 125. Defendants deny the allegations contained in Paragraph 125 of Plaintiff's
13 Complaint.

14 126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's
15 Complaint.

16 127. Defendants deny the allegations contained in Paragraph 127 of Plaintiff's
17 Complaint.

18 128. Defendants deny the allegations contained in Paragraph 128 of Plaintiff's
19 Complaint.

20 129. Defendants deny the allegations contained in Paragraph 129 of Plaintiff's
21 Complaint.

22 130. Defendants deny the allegations contained in Paragraph 130 of Plaintiff's
23 Complaint, including all sub-parts thereof.

24 131. Defendants deny the allegations contained in Paragraph 131 of Plaintiff's
25 Complaint.

26 132. Defendants deny the allegations contained in Paragraph 132 of Plaintiff's
27 Complaint.

1 133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's
2 Complaint.

3 134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's
4 Complaint.

5 **COUNT VII – FRAUDULENT CONCEALMENT**

6 135. Defendants incorporate by reference their responses to Paragraphs 1-134 of
7 Plaintiff's Complaint as if fully set forth herein.

8 136. Defendants deny the allegations contained in Paragraph 136 of Plaintiff's
9 Complaint.

10 137. Defendants deny the allegations contained in Paragraph 137 of Plaintiff's
11 Complaint.

12 138. Defendants deny the allegations contained in Paragraph 138 of Plaintiff's
13 Complaint.

14 139. Defendants deny the allegations contained in Paragraph 139 of Plaintiff's
15 Complaint.

16 140. Defendants deny the allegations contained in Paragraph 140 of Plaintiff's
17 Complaint.

18 141. Defendants deny the allegations contained in Paragraph 141 of Plaintiff's
19 Complaint.

20 142. Defendants deny the allegations contained in Paragraph 142 of Plaintiff's
21 Complaint.

22 143. Defendants deny the allegations contained in Paragraph 143 of Plaintiff's
23 Complaint.

24 144. Defendants deny the allegations contained in Paragraph 144 of Plaintiff's
25 Complaint.

26 145. The allegations contained in Paragraph 145 regarding Defendants' duty are
27 legal conclusions of law, and no answer is required. To the extent a response is required,
28

1 Defendants deny the allegations. Defendants deny the remaining allegations contained in
2 Paragraph 145 of Plaintiff's Complaint.

3 146. Defendants deny the allegations contained in Paragraph 146 of Plaintiff's
4 Complaint.

5 **COUNT IX – NEGLIGENT MISREPRESENTATION**

6 147. Defendants incorporate by reference their responses to Paragraphs 1-146 of
7 Plaintiff's Complaint as if fully set forth herein.

8 148. Defendants deny the allegations contained in Paragraph 148 of Plaintiff's
9 Complaint, including all sub-parts thereof.

10 149. Defendants deny the allegations contained in Paragraph 149 of Plaintiff's
11 Complaint.

12 150. Defendants deny the allegations contained in Paragraph 150 of Plaintiff's
13 Complaint.

14 151. Defendants deny the allegations contained in Paragraph 151 of Plaintiff's
15 Complaint.

16 152. Defendants deny the allegations contained in Paragraph 152 of Plaintiff's
17 Complaint.

18 153. Defendants deny the allegations contained in Paragraph 153 of Plaintiff's
19 Complaint.

20 154. Defendants deny the allegations contained in Paragraph 154 of Plaintiff's
21 Complaint.

22 155. Defendants deny the allegations contained in Paragraph 155 of Plaintiff's
23 Complaint.

24 156. Defendants deny the allegations contained in Paragraph 156 of Plaintiff's
25 Complaint.

COUNT X – FRAUDULENT MISREPRESENTATION

157. Defendants incorporate by reference their responses to Paragraphs 1-156 of Plaintiff's Complaint as if fully set forth herein.

158. Defendants deny the allegations contained in Paragraph 158 of Plaintiff's Complaint, including all sub-parts thereof.

159. Defendants deny the allegations contained in Paragraph 159 of Plaintiff's Complaint.

160. Defendants deny the allegations contained in Paragraph 160 of Plaintiff's Complaint.

161. Defendants deny the allegations contained in Paragraph 161 of Plaintiff's Complaint.

162. Defendants deny the allegations contained in Paragraph 162 of Plaintiff's Complaint.

163. Defendants deny the allegations contained in Paragraph 163 of Plaintiff's Complaint.

164. Defendants deny the allegations contained in Paragraph 164 of Plaintiff's Complaint.

165. Defendants deny the allegations contained in Paragraph 165 of Plaintiff's Complaint.

166. Defendants deny the allegations contained in Paragraph 166 of Plaintiff's Complaint.

167. Defendants deny the allegations contained in Paragraph 167 of Plaintiff's Complaint.

168. Defendants deny the allegations contained in Paragraph 168 of Plaintiff's Complaint.

169. Defendants deny the allegations contained in Paragraph 169 of Plaintiff's Complaint.

PUNITIVE DAMAGES ALLEGATIONS

170. Defendants incorporate by reference their responses to Paragraphs 1-169 of Plaintiff's Complaint as if fully set forth herein.

171. Defendants deny the allegations contained in Paragraph 171 of Plaintiff's Complaint.

172. Defendants deny the allegations contained in Paragraph 172 of Plaintiff's Complaint, including all sub-parts thereof.

173. Defendants deny the allegations contained in Paragraph 173 of Plaintiff's Complaint.

174. Defendants deny the allegations contained in Paragraph 174 of Plaintiff's Complaint.

PRAYER FOR DAMAGES

Furthermore, responding to the unnumbered Paragraph, including sub-parts, following the heading "PRAYER FOR DAMAGES" and beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph and all sub-parts thereof.

Further, responding to the prayer for relief as to the first cause of action for negligence against Defendants including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint. Defendants further deny that Plaintiff is entitled to any relief under Pennsylvania law.

Further, responding to the prayer for relief as to the second cause of action for negligent failure to warn against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint. Defendants further deny that Plaintiff is entitled to any relief under Pennsylvania law.

Further, responding to the prayer for relief as to the third cause of action for strict liability – failure to warn against Defendants, including sub-parts numbered 1 through 7,

1 Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny
2 that Plaintiff is entitled to any relief requested in Plaintiff's Complaint. Defendants further
3 deny that Plaintiff is entitled to any relief under Pennsylvania law.

4 Further, responding to the prayer for relief as to the fourth cause of action for strict
5 liability – design defect against Defendants, including sub-parts numbered 1 through 6,
6 Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny
7 that Plaintiff is entitled to any relief requested in Plaintiff's Complaint. Defendants further
8 deny that Plaintiff is entitled to any relief under Pennsylvania law.

9 Further, responding to the prayer for relief as to the fifth cause of action for strict
10 liability – manufacturing defect against Defendants, including sub-parts numbered 1 through
11 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants
12 deny that Plaintiff is entitled to any relief requested in Plaintiff's Complaint. Defendants
13 further deny that Plaintiff is entitled to any relief under Pennsylvania law.

14 Further, responding to the prayer for relief as to the sixth cause of action for breach of
15 express warranty against Defendants, including sub-parts numbered 1 through 6, Defendants
16 deny the allegations contained in such Paragraph and sub-parts. Defendants deny that
17 Plaintiff is entitled to any relief requested in Plaintiff's Complaint. Defendants further deny
18 that Plaintiff is entitled to any relief under Pennsylvania law.

19 Further, responding to the prayer for relief as to the seventh cause of action for
20 fraudulent concealment against Defendants, including sub-parts numbered 1 through 6,
21 Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny
22 that Plaintiff is entitled to any relief requested in Plaintiff's Complaint. Defendants further
23 deny that Plaintiff is entitled to any relief under Pennsylvania law.

24 Further, responding to the prayer for relief as to the eighth cause of action for
25 negligent misrepresentation against Defendants, including sub-parts numbered 1 through 6,
26 Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny
27
28

1 that Plaintiff is entitled to any relief requested in Plaintiff's Complaint. Defendants further
2 deny that Plaintiff is entitled to any relief under Pennsylvania law.

3 Further, responding to the prayer for relief as to the ninth cause of action for fraudulent
4 misrepresentation against Defendants, including sub-parts numbered 1 through 6, Defendants
5 deny the allegations contained in such Paragraph and sub-parts. Defendants deny that
6 Plaintiff is entitled to any relief requested in Plaintiff's Complaint. Defendants further deny
7 that Plaintiff is entitled to any relief under Pennsylvania law.

8 Defendants further deny each and every allegation not specifically admitted herein.

9 Defendants allege as affirmative defenses the following:

10 1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which
11 relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

12 2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the
13 negligence of a person or persons or entity for whose acts or omissions Defendants were and
14 are in no way liable.

15 3. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of
16 limitations and/or statute of repose.

17 4. If Plaintiff has been damaged, which Defendants deny, any recovery by
18 Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or
19 failed to mitigate their alleged damages. To the extent Plaintiff has failed to mitigate her
20 alleged damages, any recovery shall not include alleged damages that could have been
21 avoided by reasonable care and diligence.

22 5. If Plaintiff has been damaged, which Defendants deny, such damages were
23 caused by the negligence or fault of Plaintiff.

24 6. If Plaintiff has been damaged, which Defendants deny, such damages were
25 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are
26 not legally responsible.

1 7. The conduct of Defendants and the subject product at all times conformed with
2 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent
3 federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in
4 part, under the doctrine of federal preemption, and granting the relief requested would
5 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
6 violation of the Supremacy Clause of the United States Constitution.

7 8. If Plaintiff has been damaged, which Defendants deny, such damages were
8 caused by unforeseeable, independent, intervening, and/or superseding events for which
9 Defendants are not legally responsible.

10 9. There was no defect in the product at issue with the result that Plaintiff is not
11 entitled to recover against Defendants in this cause.

12 10. If there were any defect in the products – and Defendants deny that there were
13 any defects – nevertheless, there was no causal connection between any alleged defect and
14 the product on the one hand and any damage to Plaintiff on the other with the result that
15 Plaintiff is not entitled to recover against Defendants in this cause.

16 11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to
17 by other persons or entities that are severally liable for all or part of Plaintiff's alleged
18 injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is
19 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
20 either in whole or in part, from all persons or entities whose negligence or fault proximately
21 caused or contributed to cause Plaintiff's alleged damages.

22 12. Plaintiff's claims are barred to the extent that the injuries alleged in Plaintiff's
23 Complaint were caused by the abuse, misuse, abnormal use, or use of the product at issue in a
24 manner not intended by Defendants and over which Defendants had no control.

25 13. Plaintiff's claims are barred to the extent that the injuries alleged in Plaintiff's
26 Complaint were caused by a substantial change in the product after leaving the possession,
27 custody, and control of Defendants.

1 14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not
2 make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between
3 Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or
4 Defendants.

5 15. Plaintiff's claims for breach of implied warranty must fail because the product
6 was not used for its ordinary purpose.

7 16. Defendants neither had nor breached any alleged duty to warn with respect to
8 the product, with the result that Plaintiff is not entitled to recover in this cause.

9 17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate
10 warnings and instructions to learned intermediaries.

11 18. At all relevant times, herein, Plaintiff's physicians were in the position of
12 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
13 benefits of the subject product.

14 19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or
15 entities for whose conduct Defendants are not legally responsible and the independent
16 knowledge of these persons or entities of the risks inherent in the use of the product and other
17 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged
18 damages.

19 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in
20 Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical
21 conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were
22 unknown, unknowable, or not reasonably foreseeable to Defendants.

23 21. Defendants believe, and upon that ground allege, that Plaintiff were advised of
24 the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and
25 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
26 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
27 damages that Plaintiff seek to recover herein.

1 22. At all relevant times during which the device at issue was designed, developed,
2 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
3 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
4 information, and instructions, all pursuant to generally recognized prevailing industry
5 standards and state-of-the-art in existence at the time.

6 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a
7 result of the alleged conduct and do not have any right, standing, or competency to maintain
8 claims for damages or other relief.

9 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver,
10 estoppel, and/or laches.

11 25. If Plaintiff suffered any damages or injuries, which are denied, Defendants state
12 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the
13 doctrines of contributory and/or comparative negligence.

14 26. In the further alternative, and only in the event that it is determined that
15 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to
16 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,
17 any other defendants, third-party defendants, or other persons, including any party immune
18 because bankruptcy renders them immune from further litigation, as well as any party, co-
19 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

20 27. Should Defendants be held liable to Plaintiff, which liability is specifically
21 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff
22 from all collateral sources.

23 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery
24 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of
25 claims, and the prohibition on double recovery for the same injury.

1 29. The injuries and damages allegedly sustained by Plaintiff may be due to the
2 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff
3 over which Defendants had no control.

4 30. The conduct of Defendants and all activities with respect to the subject product
5 have been and are under the supervision of the Federal Food and Drug Administration
6 (“FDA”). Accordingly, this action, including any claims for monetary and/or injunctive relief,
7 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

8 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
9 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
10 their Answer to file such further pleadings as are necessary to preserve and assert such
11 defenses, claims, credits, offsets, or remedies.

12 32. The device at issue complied with any applicable product safety statute or
13 administrative regulation, and therefore Plaintiff’s defective design and warnings-based
14 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
15 comments thereto.

16 33. Plaintiff cannot show that any reasonable alternative design would have
17 rendered the G2® Filter inferior vena cava filter device as alleged in Plaintiff’s Complaint to
18 be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could
19 Defendants have known of any alternative design that may be identified by Plaintiff.

20 34. The device at issue was not sold in a defective condition unreasonably
21 dangerous to the user or consumer, and therefore Plaintiff’s claims are barred under the
22 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
23 comparable provisions of the Restatement (Third) of Torts (Products Liability).

24 35. At all relevant times during which the device at issue was designed, developed,
25 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
26 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
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28

1 information, and instructions, all pursuant to generally recognized prevailing industry
2 standards and state-of-the-art in existence at the time.

3 36. Defendants specifically plead all affirmative defenses under the Uniform
4 Commercial Code (“UCC”) now existing or which may arise in the future, including those
5 defenses provided by UCC §§ 2-607 and 2-709.

6 37. Plaintiff’s alleged damages, if any, should be apportioned among all parties at
7 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors
8 Act.

9 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
10 grossly negligent, and, therefore, any award of punitive damages is barred.

11 39. To the extent the claims asserted in Plaintiff’s Complaint are based on a theory
12 providing for liability without proof of defect and proof of causation, the claims violate
13 Defendants’ rights under the Constitution of the United States and analogous provisions of
14 the Pennsylvania Constitution.

15 40. Regarding Plaintiff’s demand for punitive damages, Defendants specifically
16 incorporate by reference any and all standards of limitations regarding the determination
17 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of*
18 *No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool*
19 *Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct.
20 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.
21 June 25, 2008) and their progeny as well as other similar cases under both federal and state
22 law.

23 41. Plaintiff’s claims for punitive or exemplary damages violate, and are therefore
24 barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of
25 the United States of America, and similar provisions of the Pennsylvania Constitution, on
26 grounds including the following:

- 1 (a) it is a violation of the Due Process and Equal Protection Clauses of the
2 Fourteenth Amendment of the United States Constitution to impose punitive
3 damages, which are penal in nature, against a civil defendant upon the plaintiff
4 satisfying a burden of proof which is less than the “beyond a reasonable doubt”
5 burden of proof required in criminal cases;
- 6 (b) the procedures pursuant to which punitive damages are awarded may result in
7 the award of joint and several judgments against multiple defendants for
8 different alleged acts of wrongdoing, which infringes upon the Due Process and
9 Equal Protection Clauses of the Fourteenth Amendment of the United States
10 Constitution;
- 11 (c) the procedures to which punitive damages are awarded fail to provide a
12 reasonable limit on the amount of the award against Defendants, which thereby
13 violates the Due Process Clause of the Fourteenth Amendment of the United
14 States Constitution;
- 15 (d) the procedures pursuant to which punitive damages are awarded fail to provide
16 specific standards for the amount of the award of punitive damages which
17 thereby violates the Due Process Clause of the Fourteenth Amendment of the
18 United States Constitution;
- 19 (e) the procedures pursuant to which punitive damages are awarded result in the
20 imposition of different penalties for the same or similar acts, and thus violate
21 the Equal Protection Clause of the Fourteenth Amendment of the United States
22 Constitution;
- 23 (f) the procedures pursuant to which punitive damages are awarded permit the
24 imposition of punitive damages in excess of the maximum criminal fine for the
25 same or similar conduct, which thereby infringes upon the Due Process Clause
26 of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the
27 Fourteenth Amendment of the United States Constitution;
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1 (g) the procedures pursuant to which punitive damages are awarded permit the
2 imposition of excessive fines in violation of the Eighth Amendment of the
3 United States Constitution;

4 (h) the award of punitive damages to the plaintiff in this action would constitute a
5 deprivation of property without due process of law; and

6 (i) the procedures pursuant to which punitive damages are awarded permit the
7 imposition of an excessive fine and penalty.

8 42. Defendants expressly reserve the right to raise as an affirmative defense that
9 Plaintiff has failed to join all parties necessary for a just adjudication of this action, should
10 discovery reveal the existence of facts to support such defense.

11 43. To the extent Plaintiff's Complaint alleges misrepresentation and fraud, these
12 allegations do not comply with the requisite of particularity under applicable procedural rules
13 and/or law.

14 44. The design complained of in Plaintiff's Complaint, the alleged defects of the
15 product, and/or any alternative design claimed by Plaintiff were not known and, in the light of
16 the existing, reasonably-available scientific and technological knowledge, could not have
17 been known at the time the product at issue was designed, manufactured, and sold. Any
18 alleged alternative design was not scientifically or technologically feasible or economically
19 practical.

20 45. Defendants reserve the right to raise such other affirmative defenses as may be
21 available or apparent during discovery or as may be raised or asserted by other defendants in
22 this case. Defendants have not knowingly or intentionally waived any applicable affirmative
23 defense. If it appears that any affirmative defense is or may be applicable after Defendants
24 have had the opportunity to conduct reasonable discovery in this matter, Defendants will
25 assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiff is not entitled to the relief demanded in Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

This 4th day of December, 2015.

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**Attorney for Defendants C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.**

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 4, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

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